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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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022,023 09/09/99 MEISSNER

P PF-200

022195
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ROCKVILLE MD 20850

HM12/0706

EXAMINER

KAUFMAN, C

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/393,023

Applicant(s)

MEISSNER ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16, 19-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14, 16, 19-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction Requirement:

Applicants election of Group I, now represented by claims 21-95 in paper number 10 filed 5/17/01, with traverse, is acknowledged. The traversal is on the ground(s) that the examination of the entire application would not constitute a burden to search because the Groups are related (*e.g.*, antibody to polypeptide, polypeptide to polynucleotide). This is not found persuasive because contrary to Applicants' assertion that any search of the prior art in regard to Group I will reveal whether any prior art exists as to Group II-V (claims 14, 16, 19 and 20), a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. For example, a search for the polypeptide must involve isolates produced by other than recombinant means. Also, nucleic acid references do not necessarily disclose a protein produced by translation of the nucleic acid. As to polypeptides and antibodies, the claimed antibodies are not required to bind only the claimed polypeptide fragment at the exclusion of other proteins. Therefore, the search for antibodies require more than searching the complete protein fragment of which it binds only a portion. For polypeptide compared to process claims, as pointed out above, a search is required for not only anticipatory references, but also those that would make obvious the invention, requiring non-coextensive searches. Therefore, restriction between groups is proper.

Applicants newly filed claims are drawn to numerous patentably distinct protein sequences and a method of producing the protein. Thus, further restriction *within* the formerly presented Group I is required, as follows:

The claims are drawn to numerous patentably distinct proteins, each of which constitutes a patentably distinct product. Applicants are required to elect a single invention of a protein, selected from the group consisting of: a protein comprising a polypeptide selected from the group consisting of the following regions of SEQ ID NO:2: Residues 1-223, 1-173, 24-223, 24-67, 24-173, 45-128, 68-173, 68-223, 129-207 and 174-223 (including polypeptides $\geq 90\%$ identical; i.e. elect one from the previous Markush group), and a single ultimate species of a

fragment of residues 1-223 which retains function (as in claim 21(k)), and a fragment of ≥ 30 amino acids of SEQ ID NO: 2.

Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein, for example it is presumed by the Examiner in setting forth this requirement that the complete protein encoded by the cDNA of ATCC deposit 97142 is SEQ ID NO: 2. To be fully responsive to this requirement, Applicants are **required** to point out which claims correspond to the elected invention.

Although the classifications for these various proteins are overlapping, for instance 530/300, each represents a patentably distinct product with distinct physical and functional characteristics. Additionally, the burden of search for the Office has increased with multiple sequences because of the rapid introduction of new sequences to public sequence databases. Further the search for more than one product would be burdensome, because some are claimed not by protein sequence, but by the sequence encoded by a nucleic acid sequence, and requires a search of the corresponding region of SEQ ID NO: 1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: 2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences; or alternatively by virtue of comprising only a small portion of a disclosed protein, which requires a separate "word search" of the protein and/or nucleic acid databases, or by claiming proteins which are not 100% identical to a disclosed protein, which requires a broader search of the protein databases. Due to the use of 'comprising' language, it cannot even be said that the search for a protein comprising amino acids 1-223 of SEQ ID NO: 2 would reveal art pertaining to, for instance, a protein *comprising* amino acids 24-67 of SEQ ID NO: 2, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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Art Unit: 1646

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

July 5, 2001